UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,215	07/08/2002	Robert J. Etches	251/037 US	6785

34312 7590 03/27/2003

CU
1042 N MOUNTAIN AVE #415
UPLAND, CA 91786

EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/486,215	etches et al.
Examiner	**Art Unit**
Joseph Woitach	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 23, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *20, 22-26, and 29-32* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *20, 22-26, and 29-32* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Feb 22, 2000* is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application is a National stage filing of PCT/CA98/00792, filed August 21, 1998.

Applicants' amendment filed December 23, 2002, paper number 9, has been received and entered. Claims 1-19, 21, 27 and 28 have been canceled. Claims 20, 22-26 have been amended. Claims 29-32 have been added. Claims 20, 22-26 and 29-32 are pending and currently under examination.

Election/Restriction

Applicant's election of Group VII in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Additionally, it is noted that claims directed to non-elected inventions have been canceled.

Claims 20, 22-26 and 29-32 are pending and currently under examination.

It is noted that a review of US provisional application 60/056,865 indicates that three inventors were named: Etches, Mohammed and Morrison, while in the instant application contains six inventors were named: Etches, Mohammed, Morrison, Wims, Trinh and Wildeman. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: PCT/CA98/00792 is not an application which can serve as a foreign application for claim of priority under 35 USC 119. Furthermore, it is noted that the instant application is a 371 National stage filing of PCT/CA98/00792.

Additionally, in review of the documentation included in the instant filing (903, 905 and supporting documents) it is noted that the claim for priority in the filing of PCT/CA98/00792 is to US provisional application 60/056,865, filed August 22, 1997. See front page of published PCT/CA98/00792 application WO 99/10505. Also, a copy of US provisional 60/056,865 has been provided as the priority document for the instant application. See WIPO information sheet and attached documents. If Applicants wish to claim benefit to US provisional application 60/056,865 a new oath or declaration should be filed indicating the correct claim for priority.

Appropriate correction is required.

Priority

For the sake of compact prosecution, if the new oath or declaration is corrected to claim priority to US provisional 60/056,865 it is noted that Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

> An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Presently, because the instant application is a national stage filing of PCT/CA98/00792 it is accorded the effective filing date of August 21, 1998.

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes. However, it is noted that figure 4 is illegible and the information presented in this figure has been interpreted in light of the information provided by the figure legend (page 6, lines 1-4).

Claim Objections

Claim 31 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, independent claim 20 specifically requires that a variable region is encoded by the DNA sequence. It is known in the art that the variable region of an antibody is the portion of the antibody which recognizes the antigen to which an antibody binds (see also the instant specification, page 1, lines 25-27). Thus, the limitation that the variable region 'is specific for an antigen' is non-limiting because this is an inherent property of the variable region of an antibody.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 29-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Specifically, the embodiments of (1) egg-laying chickens 'whose somatic lymphoid cells contain an expression system" and (2) producing "345 ng of human gamma isotype immunoglobulin per ml of egg yolk" are considered new matter. First, with respect to the

expression system being in the 'somatic lymphoid cells' of the chicken it is noted that the specification generally supports that expression system is provided to all somatic and germ cells (see for example original claims and page 14, lines 18-20). While the specification supports generating chimeric animals wherein 'a lymphoid cell line' is generally contemplated, the specification provides no literal support for providing the expression system specifically to the 'somatic lymphoid cells' of the chicken. Further, the specification provides no figurative support for this embodiment because it provides only general means of introducing expression systems into a chicken and it fails to teach any specific methodology to target specifically the somatic lymphoid cells of the chicken. Second, with respect to the limitation of '345 ng' of protein produced, it is noted that the specification supports various specific amounts of antibody produced and delivered to the egg (see for example page 22 and working examples), however the specific limitation of 345 ng/ml finds no literal or figurative support in the instant specification. The closest number Examiner can find upon review of the specification is in Table 2 (at line 20) which contains one example wherein 3.46 ng/ml yolk is produce in one egg at one specific time point, however this is not 345 ng/ml, nor does it support that this amount would be produced at any other time point

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 20, 29-32 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make

and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure. Examiner has reviewed the portions indicated by Applicants in support of the newly amended claims (see Applicants' amendment page 5) and has further reviewed the entire specification, however has not found the necessary support for the two new limitations discussed above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 22-26 and 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claims 20 and 22 are vague and unclear in the recitation of 'an undisrupted CH2-CH3 interface' (final line of both claims 20 and 22). Upon review of the instant specification a CH2-CH3 interface is not specifically defined, and it is unclear with what the CH2-CH3 region interfaces and what is undisrupted within the CH2-CH3 region or between the interface. More clearly defining what is encompassed by 'interface' or more clearly setting forth the nature of the encoded antibody would obviate the basis of the rejection. Dependent claims 23-26 and 29-32 are included in the basis of the rejection because they encompass this embodiment but fail to further clarify the basis of the rejection and only provide further unrelated limitations.

Claim 31 is unclear and confusing in the recitation of a 'variable region that is specific for an antigen' because a variable region of an antibody is the portion of the antibody which binds to the epitope to which the antibody is produced (see for example page 1 of the specification, starting on line 25). It is unclear how this limitation further limits the immunoglobulin variable region set forth in independent claim 20 because the variable region of an immunoglobulin is specific to an antigen. Further, the metes and bounds are indefinite because the nature of what is considered 'specific' is not clearly set forth. The claim is drawn generically to any antigen, however the variable region must specifically bind to an antigen. Without setting forth what is

encompassed by the term 'specific' the metes and bounds of the claim can not be defined because the nature of any binding considered to be 'specific' is not and can not be specifically determined.

Claims 20, 23-26 and 29-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116. In the instant case, while a written description for "an immuglobulin-gene derived promoter sufficient for expression on the human immunoglobulin constant region in the chicken" lacks written description (independent claims 20 and 22). It is noted that the specification teaches that preferred regulatory sequences are derived from immunoglobulin genes (page 8, lines 20-24), however the specification fails to provide any clear guidance to what the specific regulatory sequences would be, and more specifically, what derivation would done or required for

expression in chickens. The claims are very broad encompassing a promoter obtained from any species of animal. The only support for this embodiment is the general recitation for the use of such a promoter, however the specification provides no specific examples of such a promoter nor any specific methodology for obtaining such promoter sequences. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998). In the instant case, Applicants have asserted the preferred use of promoter sequences from an immunoglobulin gene which are derived to provide expression in the chicken, however the specification fails to describe the relevant structural and identifying characteristics of any of the nucleic acid sequences of any of the gene sequences which meet this limitation that can be used in the instantly claimed chicken or method. Adequate written description requires more than a mere statement that it is part of the invention or a reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

Applicants attention is drawn to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein it was stated:

In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. *A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is*. (*emphasis added*, See *Fiers,* 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*)). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Similarly in the present situation, the claims are very broad encompassing promoters derived from any species of animal and simply reciting that promoters are derived from immunoglobulin genes is not adequate description of promoter sequences which would provide expression in chickens. The specification provides only the general support that an immuglobulin-gene derived promoter would be a preferred embodiment, however the specification does not provide a single species of such a promoter which is sufficient for expression in the chicken, nor any specific description of important structural elements which the

promoter requires, and the specification is silent with respect to any specific methodology for deriving such promoter sequences.

Conclusion

No claim is allowed. The claims are free of the art of record, however they are subject to other rejections.

At the time of filing the mechanism of delivery of the endogenously produced antibody was not known, and because the shared homology between chicken IgY and human IgG antibodies is low, there was no expectation that heterologous human antibody produced in or provided from lymphoid cells would be effectively delivered to the egg of a chicken. Further, at the time of filing it was known that endogenously produced chicken antibodies could be delivered to the egg of an egg-laying chicken, however while the prior teaches that proteins can be produced in chickens, the means of targeting the protein to the egg was by virtue of expression in the oviduct of the chicken where the egg is formed (see for example WO 94/20608), not in cells present in the general circulation such as lymphoid cells.

The art made of record and not relied upon is considered pertinent to applicant's disclosure:

Mohammed *et al.* Immunotechnology 4:115-125.

Harvery *et al.* Nature Biotechnology 19:396-399.

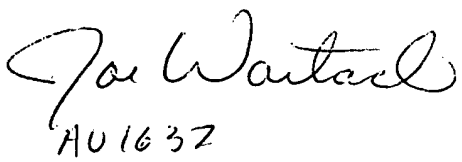
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

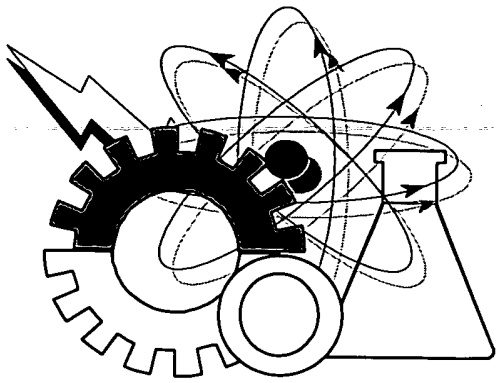
Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach



Joseph T. Woitach
Patent Examiner USPTO
(703) 305-3732 phone
(703) 746-5192 fax



Fax

To: Kurt T. Mulville

Fax: (949) 567-6710 **Pages:** 16 (including cover page)

Phone: (949)657-6700 x7740 **Date:** December 4, 2003, 2003

Re: 09486,215

☐ **Urgent** ☑ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• **Comments:**

Dear Mr. Mulville,

Attached is a copy of the action mailed March 27, 2003, paper number 10. Because the action was mailed to the incorrect address, this duplicate action is being mailed and the time for reply has been reset from the day of the re-mailing.

If you have any further questions or problems, please contact me.

Sincerely,

Joe Woitach

Joseph Woitach